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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,139	09/27/2004	Reddy Bandi Parthasaradhi	H1089/20010	1949
3000 7590 07/12/2007 CAESAR, RIVISE, BERNSTEIN, COHEN & POKOTILOW, LTD. 11TH FLOOR, SEVEN PENN CENTER 1635 MARKET STREET PHILADELPHIA, PA 19103-2212			EXAMINER CHANG, CELIA C	
			ART UNIT 1625	PAPER NUMBER
			MAIL DATE 07/12/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/509,139	<b>Applicant(s)</b> PARTHASARADHI ET AL.	
	<b>Examiner</b> Celia Chang	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) \_\_\_\_\_ is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. This application is a 371 of PCT/IN03/00066 filed Mar. 24, 2003.  
Claims 1-16 are pending.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-7, 15 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,943,590.

See col. 6, lines 66-68, col. 10, claims 1 and 3.

Please note that the instant claims and the prior art disclosure different in the measurements of crystallinity by powdered X-ray diffraction. Please note that the innate nature of a product, such as the X-ray diffraction pattern does not demarcate from a product which although was not measured by X-ray but are made by the same identical process of crystallization from acetone as the claims.

It is well recognized in the art that X-ray diffraction pattern although useful must be carefully evaluated (See US Pharmacopoeia). Small difference in X-ray lines does not necessarily imply new forms. In addition, it is well known that powder X-ray pattern are unreliable without factual evidence in comparative measurements that artifacts are not at issue (see Davidovich et al.) and the same crystal when taken in powdered process can provide misleading pattern (see Bernstein p. 118) while same X-ray pattern can be different compounds. Such degree of understanding offered the scientific basis that powdered X-ray diffraction pattern alone absent of complete multiple character of a product which was made by identical process does not demarcate from the prior art. Thus, anticipation was found.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 10, 13, 16 rejected under 35 U.S.C. 102(e) as being anticipated by US 6,916,941.

See col. 5-6, examples 1-2.

Please note that the instant claims and the prior art disclosure different in the measurements of crystallinity by powdered X-ray diffraction. Please note that the innate nature of a product, such as the X-ray diffraction pattern does not demarcate from a product which although was not measured by X-ray but are made by the same identical process of crystallization from acetone as the claims.

It is well recognized in the art that X-ray diffraction pattern although useful must be carefully evaluated (See US Pharmacopia). Small difference in X-ray lines does not necessarily imply new forms. In addition, it is well known that powder X-ray pattern are unreliable without factual evidence in comparative measurements that artifacts are not at issue (see Davidovich et al.) and the same crystal when taken in powdered process can provide misleading pattern (see Bernstein p. 118) while same X-ray pattern can be different compounds. Such degree of understanding offered the scientific basis that powdered X-ray diffraction pattern alone absent of complete multiple character of a product which was made by identical process does not demarcate from the prior art. Thus, anticipation was found.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boegesoe et al. US 4,943,590 or Christensen et al. US 6,916,941. In view of Cheronis supplemented with Sanches et al. US 6,960,613, US 6,768,011 or US 7,112,686 .

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Boegesoe et al. '590, col. 6, lines 66-68, col. 10, claims 1 and 3 or Christensen et al. col. 5-6, examples 1-2. disclosed products prepared by identical processes which anticipated the claims (see section 3 supra).

*Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)*

The difference between the instant claims and the prior art product is that the powdered X-ray diffraction pattern was included or a variation of solvent was employed in preparing the product. Cheronis taught that crystallization/recrystallization is a routine laboratory tool in purifying compounds. The employment of variation of common laboratory solvent would be an routine operation for such process (see p. 31-33). Sanches '613 taught that for the particular compound citalopram oxalate, the same obvious routine recrystallization skill in purification is desirable (see col. 3, lines 30-35); Rock et al. '011 disclosed the employment of acetone for crystallization (see col. 6, line 1); Humble et al.(102(e) reference) taught that recrystallization of enantiomeric citalopram oxalate can employ alcohols, ketones, acetonitrile etc. (see col. 5, lines 22-25, col. 6, lines 8-11).

*Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)*

One having ordinary skill in the art is well aware of all the pertinent art in the field. The above references provided the particular process to obtain the crystalline forms of s-citalopram oxalate with suggestions that further purification is desirable using routine recrystallization skill with common laboratory solvents. Further motivated by the operable solvents employed by analogous art, the particular choices among the common laboratory solvents are well delineated and suggested. In absent of unexpected results, the mere carrying out of routine purification or laboratory measurement of a known product is prima facie obvious **because** continuous purification of a pharmaceutical product is always a desirable modification of the known compound, especially, the selection of solvents are well delineated in the art. Further, the

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measurements of physical characterization of a purified product is the innate nature inseparable from the product per se absent of comparative and unexpected results.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang  
July 5, 2007

  
Celia Chang  
Primary Examiner  
Art Unit 1625